Instruction manual

Homecarebed

„ECOFIT ULTRA “

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CE

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Contents

Please read and observe this Instruction Manual before each use!
In the event that the care bed changes owners, please supply this Instruction Manual to the new owner!

Foreword

Dear Customer,

The team from TekVor Care would like to thank you for the confidence you have placed in our ECOFIT ULTRA care bed.

With your decision to buy a care bed from TekVor Care you have a care product with a high degree of functionality and the highest level of safety.
With the care bed you have purchased we can guarantee maximum comfort and a professional standard of care.
All beds are scrupulously tested by our company before leaving our premises.
The care bed delivered to you left our factory in perfect condition.

When you accept delivery of the care bed, the responsibility for proper use according to the purpose intended passes to you at the same time.

This instruction manual informs you as the operator and your users about the functions and safe handling of this care bed on a daily basis.

Please keep the instruction manual near the care bed at all times.

We are confident that this product will play an important role in care-giving.

Yours sincerely

TekVor Care Team

1 General Information

Before putting the bed into service for the first time:
Read through this instruction manual conscientiously from start to finish!
Please note in particular that the various safety instructions must be observed.
Clean and disinfect the care bed before using it for the first time.

TekVor Care care beds bear the CE mark and meet all safety and functionality requirements. These care beds were tested according to the international standards which contain the safety requirements for medical products.
These safety requirements can only be met however if the user satisfies himself of the proper state of the care bed (including accessories) before using the bed.

Please observe the Operators of Medical Products Ordinance (Medizinprodukte-Betreiberverordnung, German abbreviation: MPBetreibV).

General Information:	§2 (MPBetreibV)
Operation and use:	§5 (MPBetreibV)
Storage of Instruction Manual:	§9 (MPBetreibV)

1.1 Explanation of the Symbols Used

Read information with this symbol carefully and urgently follow instructions.
This information is safety-relevant.

This symbol indicates hazards due to electrical voltage. There is mortal danger!

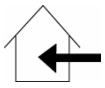
This symbol indicates general hazards. There is danger to life and health.

Conformity mark in accordance with the Medical Device Directive (93/42 EEC).

IPX6 The electrical equipment is suitable for automated washing systems.

Symbol for Protection Class II device, shock-proof.

Symbol for type B device according to DIN EN 60601-1.



This care bed may only be used indoors

This product must be disposed of in a separate refuse collection in the European Union. Do not dispose of as normal domestic waste.


Symbol for direct current.


Symbol for alternating current.


Maximum permissible load.


Maximum patient weight.


Read instructions

1.2 Definition of the Groups of Persons Involved

Operator
An operator is any natural or legal person who uses the care bed or on whose instruction it is used (e.g. nursing homes, specialised retailers, health insurance companies, medical suppliers).

Users
Users are persons who as a result of their vocational training, experience or briefing are authorised to operate the care bed or to carry out work on it, or are instructed in handling the bed. Furthermore the user can recognise and avoid potential dangers and assess the clinical condition of the patient.

Patient / Occupant
Persons in need of care, handicapped or infirm and occupying a care bed.

Qualified Personnel
Qualified personnel are employees of the operator who as a result of their vocational training or briefing are entitled to deliver, assemble, disassemble and transport the care bed. In addition, these persons are instructed in the cleaning and disinfection regulations for the care bed.

2 Intended Purpose

2.1 Use for the Purpose Intended

This care bed is intended for accommodating patients or occupants (with body mass ≥150 cm to max. 170 kg) in residential homes, nursing homes and in care in the home (application environments 3 and 4) and may only be used under the conditions for use described in this Instruction Manual.
It is used to alleviate or compensate for handicaps or disabilities and to facilitate the working conditions for the carer.

Any other use shall be regarded as non-compliant with the regulations and is excluded from any liability.

Attention: The care bed is **not** designed for use in **hospitals.**
The care bed is **not** suitable for **medical electrical applications** which involve intravascular or intercardiac processes with the patient.
The care bed is **not** designed for the **transport** of patients.

Under certain conditions the care bed can be used for other medical purposes with medical appliances such as antidecubitus mattresses, aerators, alimentation systems etc. In this case all bed functions **must be locked out with the nurse key** on the handset for safety. The medical appliance providers are liable for the compliance of the device with the directives of IEC 60601-1-1. If other electrical devices are used in the bed and to prevent the risk of an electrical shock, **protective measures and precautions must be established to prevent power cords from being trapped and squeezed** in movable parts of the bed.

2.2 Non-compliant Use

All uses deviating from the intended purpose, which may also be hazardous as a result.

This includes for example:

- Loading the care bed beyond the safe admissible working load (see section 13.1 and identity label on bed frame)
- Operation of the care bed by patients or occupants who have not been instructed in its use
- Use of the care bed for children
- Attempting to move the care bed when it is in a braked position
- Use of the care bed on a non-horizontal surface (max. incline 5°)

3 General Regulations for Users

The care bed must only be used for the purpose intended. When setting up, operating and using the care bed, the regulations of the Medical Products Act (German abbreviation: MPG, Medizinproduktgesetz) and the legal provisions decreed in this respect, the general recognised rules of technology and the occupational health and safety and accident prevention regulations must be complied with.
If the care bed is in a faulty state, in which the patient/occupant, care personnel or third persons could be endangered, operation may not be started.

3.1 Qualification of Users

The care bed must only be operated by persons who have the corresponding training or experience to enable them to handle the care bed correctly.

4 Safety Instructions

4.1 General Safety Instructions

During the briefing, specific attention must be drawn to any potential dangers which can occur despite correct operation. Before putting the care bed into service for the first time, the Instruction Manual must be read conscientiously and in detail by the user / care personnel.

When operating the adjusting functions, there must not be any objects or people's limbs in the plane of movement of the care bed. Risk of crushing!

Do not sit on the leg section of the bed when operating the raise function.

Ensure that children cannot operate the control system and check if pets are under the bed before operating any of the function. Never store anything under the bed.

If the physical or mental state of the patient requires, the handset should be locked on the reverse side of the handset when not in use (nurses' key). See detailed description of the locking operation at section 7.3. (it may be advisable to keep the handset out of reach of such a patient to avoid the risk of strangulation with the handset cord).

Adjustments to the bed must only be carried out by suitably instructed persons or in the presence of an instructed person.

When the side guards are used, the following instructions must be particularly adhered to:

- Use only approved side guards supplied as option by TekVor Care. See suitable dimensions at section 13.1.
- Only suitably instructed personnel are allowed to operate the side guards.
- Side guards must only be adjusted to be either fully up and locked in place or fully down.
- When operating the adjusting functions, the patient's limbs must not protrude beyond the mattress base or touch the side guards.
- The side rail guards are only designed to prevent a person falling out of the bed; under no circumstances should they be climbed or leaned on.
- When lowering the rails take care not to drop them, they should be lowered carefully.
- The side guards only provide protection against rolling out of the care bed if the backrest and lower leg adjustments are in the horizontal position.
- The side guard height from the top of the mattress in uncompressed condition must be at least 220 mm. If the height is less than 220 mm increase the side guard height with a high side rail kit.
- The gap between 2 side guard rails or between lower side rail and bed platform must be less than 12 cm.
- During use ensure that the side guards are level.

Unplug the mains plug from the socket before moving the care bed and take care to avoid dragging the mains plug across the floor when moving the bed.

The mains plug must always remain accessible to enable immediate cut-off by unpluging the mains plug from the wall socket in case of emergency.

The mains cable must be free and not caught up in anything, as it gets carried along when the bed height is adjusted. Otherwise, the mains cable may be torn out of its strain relief and damaged. In addition, the mains plug may be pulled out of its socket and electric leads exposed as a result.

Please check all fixings on your bed at least once a month. Pay special attention to side rail components and sleeping platform connections.

If the mains cable or the mains plug are damaged, the relevant part must be replaced. This work should only be carried out by the manufacturer or authorised professionals.

When connecting the mains plug do not use multiple sockets since liquids may penetrate into these (fire hazard and electric shock).

Before cleaning and disinfection the mains plug must be unplugged and hung up safely. Plugs for the handset and the motors which are inserted into the mattress base motor unit must remain plugged in. This is necessary to prevent water from penetrating into the motor unit.

When the bed is stationary the castors must always be in the braked position. If the castors are not braked, the bed can move when the occupant gets into and out of bed, since the occupant uses the bed for support. Injury can result if the care bed rolls away.

In order to move the care bed, the brake on all four castors must be released and the mattress base be adjusted to the lowest horizontal position.

The maximum duty cycle and the safe working load must not be exceeded as otherwise safe operation cannot be guaranteed (please refer to Technical Data).

The bed must not be used in rooms where there is a risk of explosion.

The bed must only be taken apart if there is no patient or occupant in it.

4.2 Safety Information for the Operator

With the help of this Instruction Manual, instruct each user in the safe operation of this care bed before it is put into service for the first time.

Advise the user of any hazards which may occur if not handled correctly.

Only persons who have been properly instructed may operate this care bed. This also applies for persons who only operate the care bed on a temporary basis.

According to the Medical Products Act (German abbreviation: MPG, Medizinproduktgesetz), care beds are Class I active medical products.
Please observe your obligations as the operator in accordance with the Operators of Medical Products Ordinance (Medizinprodukte-Betreiberverordnung, German abbreviation: MPBetreibV), in order to ensure the permanently safe operation of this medical product with no risk of danger to patients, users or third parties. If the care bed is used on a long-term basis, checks for proper functioning and for any visible damage must be performed and documented at least once a year. There is section 10.2 for this purpose.

4.3 Safety Information for the User

Ensure that the operator instructs you in the safe operation of this bed.

In addition, pay particular attention to the general safety information as described in 4.1. Adjustments of the bed must only be carried out by suitably instructed persons or in the presence of an instructed person.

Make sure that the mattress base has travelled to its lowest position before leaving the patient unattended. This will minimise the risk of injury to the patient when getting in or out of bed.

If there is a suspected fault or damage, unplug the mains plug from the socket. Clearly mark the care bed as "Out of Order" and take it immediately out of service. After that please inform the operator in charge without delay.

4.4 Cleaning and Disinfection

The bed including electrical components is IPX6 suitable for automated washing systems.

Before cleaning and disinfection the mains plug must be unplugged and hung up safely.

Please note all the plugs must be fitted into the control box to keep the componants water tight. Please also check the condition of the rubber o rings on the sleeping platform joints, if the o rings are damaged or missing they must be replaced.
DO NOT WASH THE BED WITHOUT INTACT O RINGS FITTED.

Always wear waterproof gloves when cleaning and disinfecting to avoid skin irritation.

Attention: In the event of disinfection by spraying on a large scale with products containing alcohol there is a danger of explosion and fire.

4.5 Servicing and Maintenance

Servicing work must only be carried out by persons who have at least read the safety regulations and are qualified according to the MPBetreibV (Operators of Medical Products Ordinance) § 4 and 6.

A technical check and/or safety inspection must be conducted at least once a year and after a lengthy break in use. There is section 10.2 for this purpose.

Any defects, damage or signs of wear must be eliminated without delay. Only original spare parts from TekVor Care may be used, otherwise all guarantees or warranties will be excluded.

Please check all fixings on your bed at least once a month. Pay special attention to side rail components and sleeping platform connections.

The 9V block battery is the energy store for electrical emergency lowering in the event of a power failure. The energy store is sufficient for one emergency lowering at the most

and must then be replaced. If the expiry date of the battery has elapsed then it must be replaced immediately. Since batteries are subject to self-discharging, it is recommended that the battery is replaced every two years if not used. It must be ensured that it is a type 6LR61 alkaline manganese battery and not any other type . Used batteries must be disposed of in an environmentally compatible way.

4.6 Accessories

The optional accessories available include a patient's lifting pole of which the safe working load is 80 kg **and must not be exceeded**. The patient's lifting pole may only be used within its admissible adjusting range which is defined by the sleeve on the bed. Otherwise the whole bed can tip up and result in serious injury.

Use only mattresses compatible with the supplied side guard system. The dimension between mattress upper surface in uncompressed condition and top edge of the upper side rail must be 22cm minimum. If this dimension is less than 22cm, a high side rail kit should be fitted. In general mattresses of 12 cm height are suitable.

4.7 Electromagnetic Compatibility

Regarding their emitted interference and interference resistance the electric motor units comply with the requirements of EN 60601-1-2:2007 (see section 13.7). But it is possible that electrical devices interfere with each other. In this case switch off the care bed for a short time or remove the interference source. We refer to the position paper of the BfArm reference n° 9/0508 (Bundesinstitut für Arzneimittel und Medizinprodukte).

4.8 Storage

If the care bed is stored for a lengthy period, the 9V block battery should be removed, as otherwise it would be subject to a higher rate of self-discharge.

4.9 Service Life and Disposal

The normal service life for care beds in domestic use is approx. 5 years. The care bed must not be disposed of as normal domestic waste after its service life has expired. To ensure that it is disposed of in an environmentally compatible way please get in touch with TekVor Care.

5 Storage and Transport

Due to its modular construction the care bed can be easily transported. This is made possible by a transporting device. The care bed integrated in the transport rack can be manoeuvred in very small spaces due to the bed's castors.

State as delivered

Care bed in the transporting device

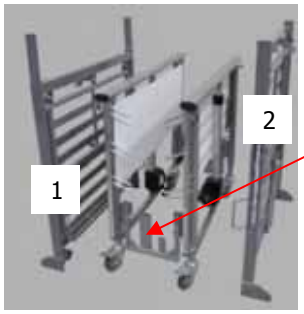
Please do not dispose of the cover! This can be used again as a dust cover in the event that the care bed is later stored in the transport rack.

6 Installation and Commissioning

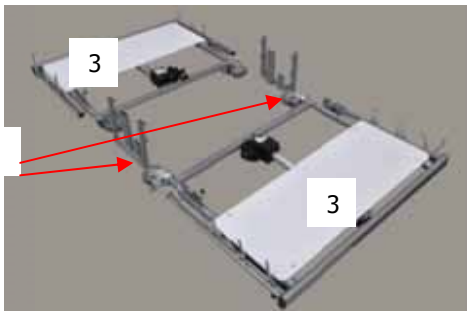
6.1 Pre-installation inspection

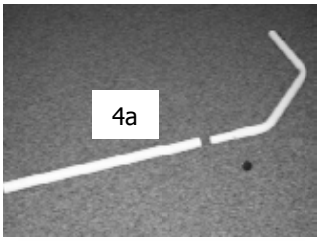
On delivery and before installation check that the packaging is undamaged. Report any visible damage to the transport company immediately.

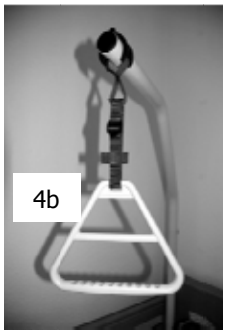
After unpacking check that all following parts are present:

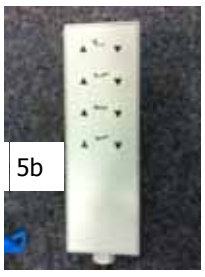


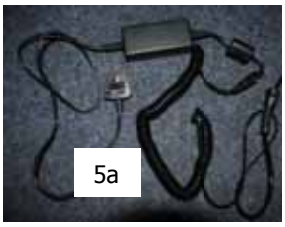
Transportvorrichtung











6 aluminium side guards with caps delivered with the base as a separate package!

6b

- Backrest section with mounted backrest actuator and control box
- Legrestsection with mounted kneebreak actuator
- 2x height adjustable bed ends with mounted actuators and castors
- (4a) Monkey pole (optional) with triangle grip and strap (4b)
- (5a) power supply with cord and plug

- (5b) handset with locking device
- (6a) 6 pcs. aluminium sideguards and 12 plastic end caps (6b) in a separate package
- Instruction manual

6.2 Removal from the Transporting Device

Lift the cover from the whole bed unit including the transporting device.

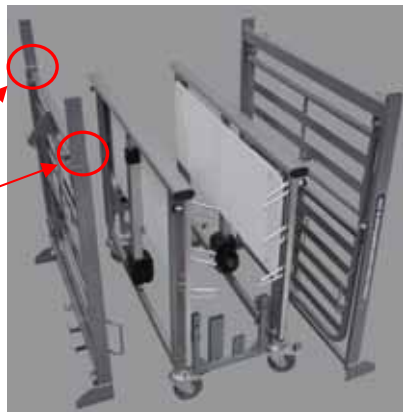
Cut through the packaging strips using a side cutter or a pair of scissors

First lift the mattress base section for the foot-end out of the transporting device and then lift out the mattress base section for the head-end of the bed.

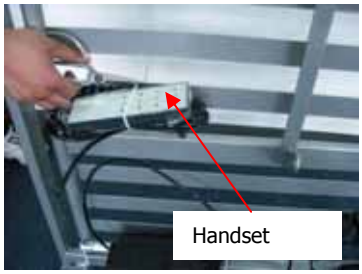
1. Mattress base section for the foot-end

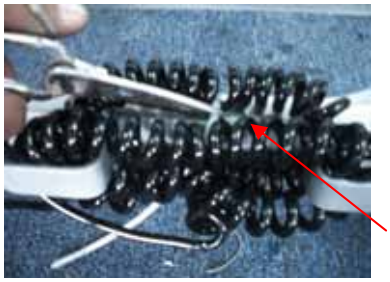
2. Mattress base section for the head-end

Check the condition of the rubber o rings here. If they are damaged or missing they should be replaced immediately. Two spare o rings are supplied and fixed to the platform.



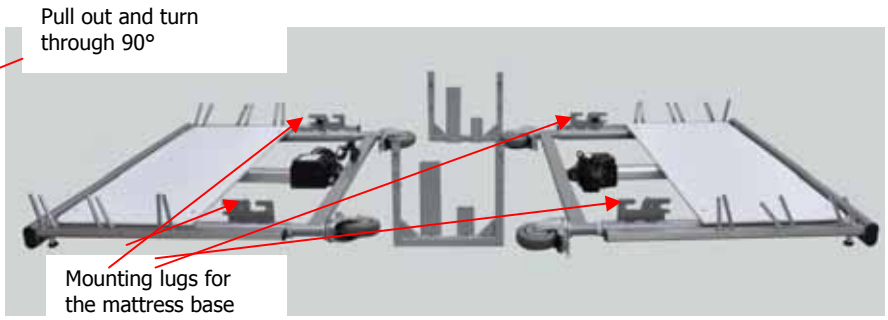
Remove the cable ties from the handset and the mains cable.





Mains cable, Caution!
Do not damage the cable!

Remove the height-adjustable head and foot end panels from the transporting device. To do this, release the spring-loaded catches that are later used to fix the height-adjustable head and foot end panels to the mattress base.



6.3 Assembly of the Care Bed

Remove the cable tie from the backrest motor (including the attached mains adapter) and from the thigh rest adjustment motor. Attention! Keep firmly hold of the motor in question when loosening the cable tie, because the motors can fall when they are not secured in place (with safety bolts).

Backrest motor

Thigh rest adjustment motor

Please note
The actuators arrive in the transport position.
If the bed is operated with the actuators in this position it will result in the premature failure of the actuator/sleeping platform.
Remove the safety bolt then move the actuator into position and re install the safety bolt.

Connect the fork heads of the motor units with the terminal links on the mattress base. To do so, use the safety bolt which is inserted into the hole for the terminal links. In order to loosen the bolt, throw the safety lever. Attention: The safety lever must be locked again after connecting the motor and the mattress base.

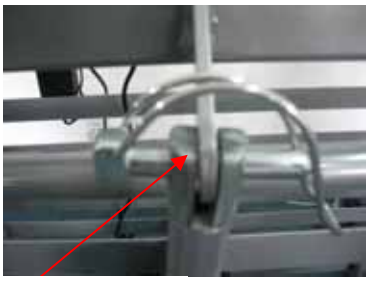
Backrest motor situation

Mattress base
terminal link

Thigh rest motor

Safety bolt

Final secured state



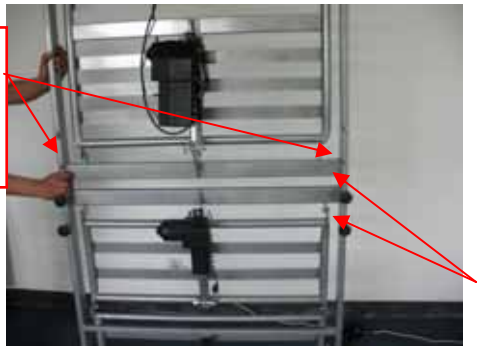
Safety lever,
fixed in place

Please also check the condition of the rubber o rings on the sleeping platform joints, if the o rings are damaged or missing they must be replaced.
DO NOT WASH THE BED WITHOUT INTACT O RINGS FITTED.

Connecting the two halves of the mattress base

Now fit the two halves of the mattress base together and secure them using the star knobs provided.

Check the condition of the rubber o rings here. If they are damaged or missing they should be replaced immediately.



Star knobs M8 (4x)

After assembling the mattress base halves, tighten the star knobs.

Now lay the mattress base on the floor and attach the first of the bed ends to the mattress base. To do this, apply the brakes on the bed castors by pressing the brake pedal and then release the spring-loaded catches (see 6.1) at the height-adjustable head and foot end panels so that the mattress base can be slotted onto the mounting lugs.

Foot pedal locked

Castor

Spring-loaded catch

Snap the spring-loaded catches back into place on both sides

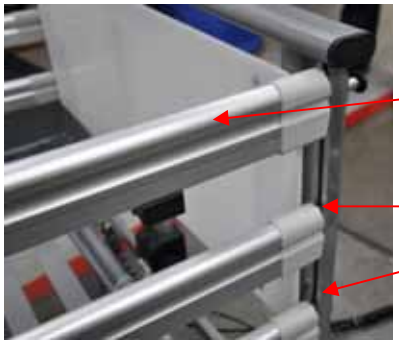
Mounting lugs for the mattress base

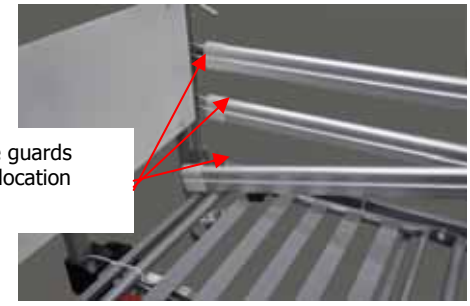
Mattress base

The bolt of the spring-loaded catch must be securely latched into the hole!

When securing the spring-loaded catches, ensure that the bolt locks into place in the hole provided for it.

Now slot the mattress base into place on the second height-adjustable bed-end panel at the other end of the bed.
*Do not lock the spring-loaded catches on this side just yet, because these must remain open until the aluminium side guards have been mounted. Now slide the (six) side guards onto the location bolts of the side guard guides, resting the other ends of the side guards on the mattress base at the other end of the bed.





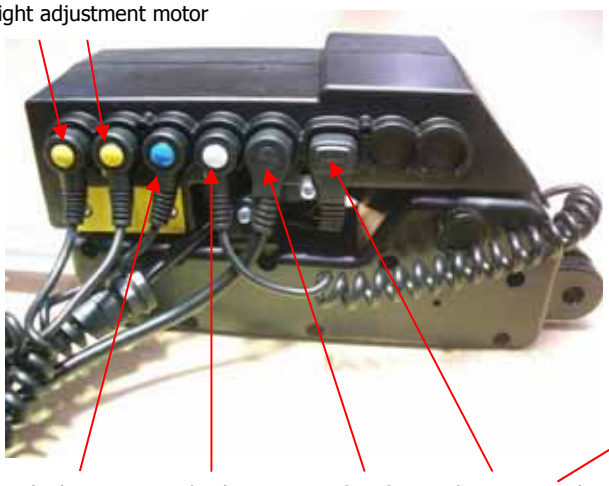
Now, *with the side guards slotted into place*, the end panel can be pushed back up to the mattress base and secured with the mounting lug. Repeat this procedure on the other side of the bed with the remaining three side guards and then fix the two spring-loaded catches securely to the mattress base.

Now connect the height adjustment motors and the thigh rest adjustment motor to the mains power supply. First remove the plug cover by unscrewing the two fixing screws. The power supply cables for the height adjustment motors are wound around its housing. The backrest motor is supplied already plugged in. After you have inserted all the plugs, screw the plug cover back onto the power supply unit housing.

Fixing screws of plug cover

Unwind the cable of the electric motor!

Height adjustment motor



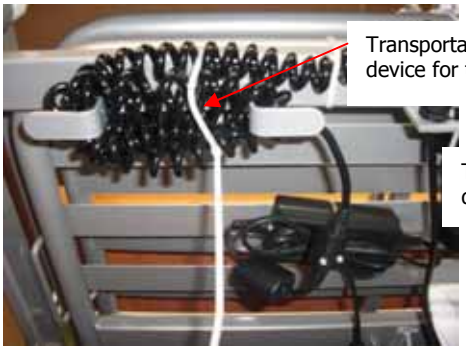
Thigh rest motor, backrest motor, handset and power supply are supplied already plugged in!

Power supply includes: UK mains plug-cable to Safe Low Voltage Transformer.
Cable and connectors from Transformer to control box.

Height adjustment motor

Height adjustment motor

Now remove the transportation s attress base by cutting through the cable ties with a side cutter or a knife.

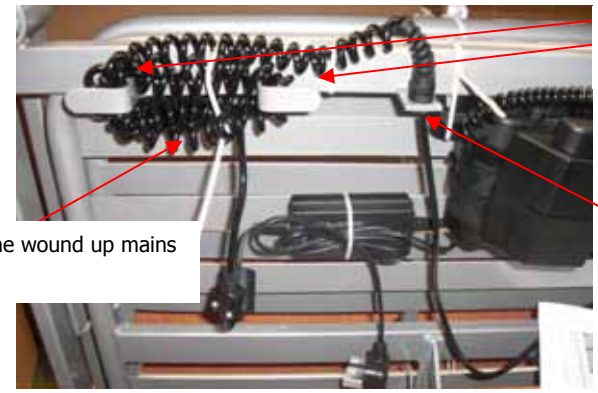


Transportation safety device for the thigh rest

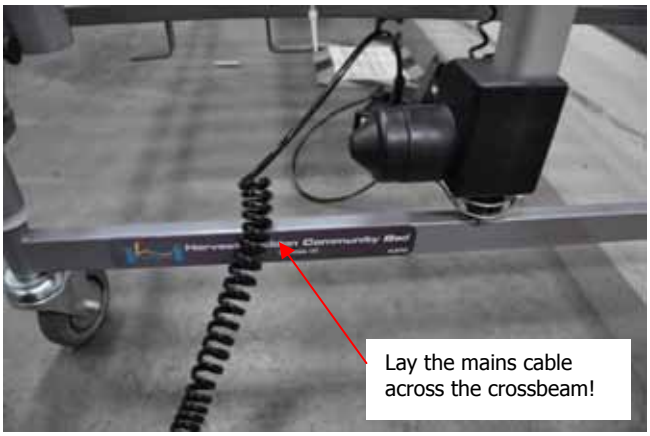
Transportation safety device for the backrest

Connecting the care bed to the mains socket

Unwind the mains cable wound up under the mattress base.



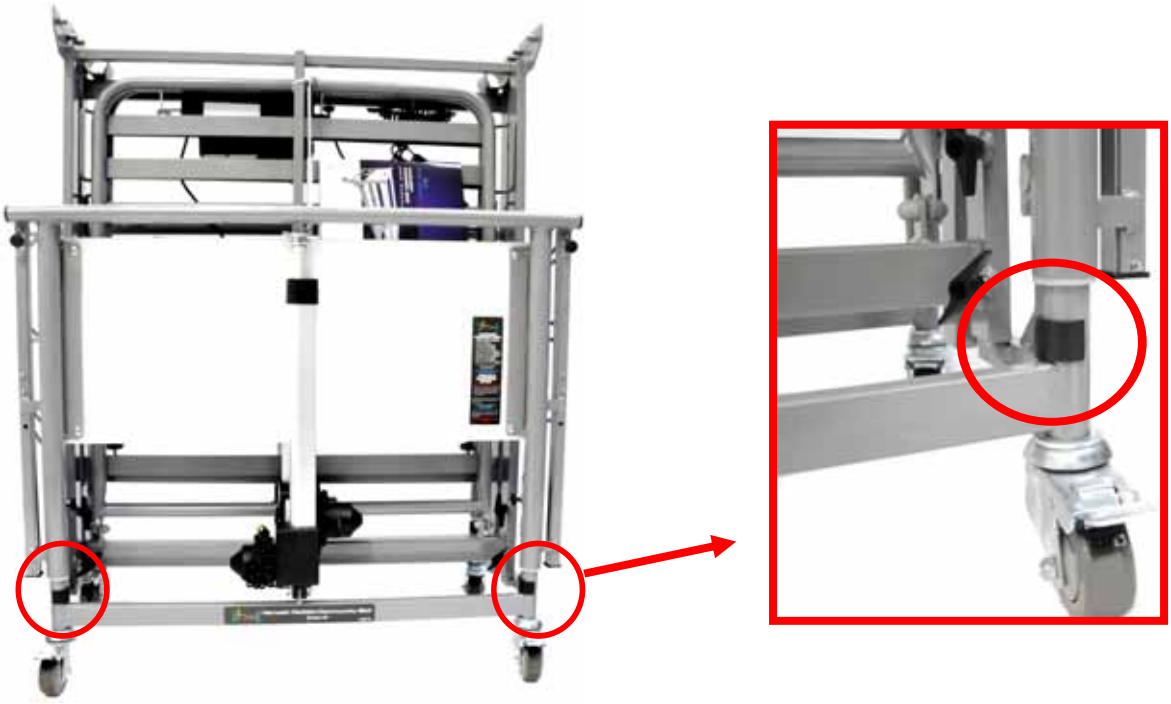
Lay the coiled cable across the crossbeam from the head or foot end as shown in the picture.
This reduces the risk that the mains cable is driven over when the bed is moved. Always avoid driving over the mains cable!



Plug the mains plug into the socket. The mains plug must always remain accessible to enable immediate cut-off by unpluging the mains plug from the wall socket in case of emergency.
The electrical adjustment motors are now ready for use.

Important notice

Before the bed is put into service please remove the 4 transport clips
from above the castors. These should be retained and re used if the bed is fitted back on to its transport brackets.
See picture.



6.4 Placing into service

Make sure that all assembly steps have been carried out according to chapter 6, section 6.1 and 6.2

Do a safety check according to chapter 10, section 10.2 after assembly.

Clean and disinfect the bed as described in chapter 8 before putting into service and before each further use.

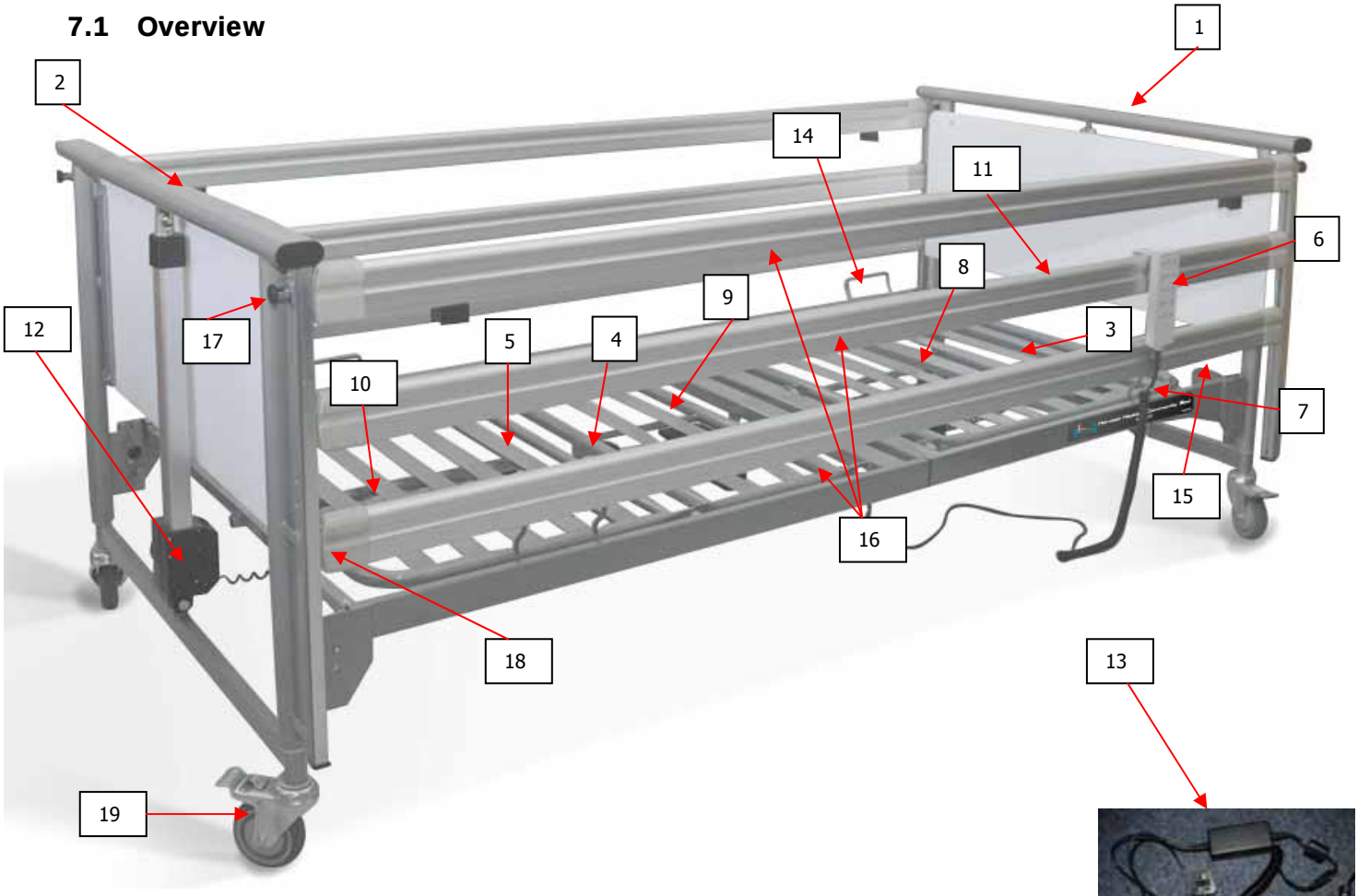
6.5 Disassembly of the Care Bed

Unplug the mains plug from the socket before disassembly!

Disassembly of the care bed is carried out in reverse order of assembly.

7 Description of Functions

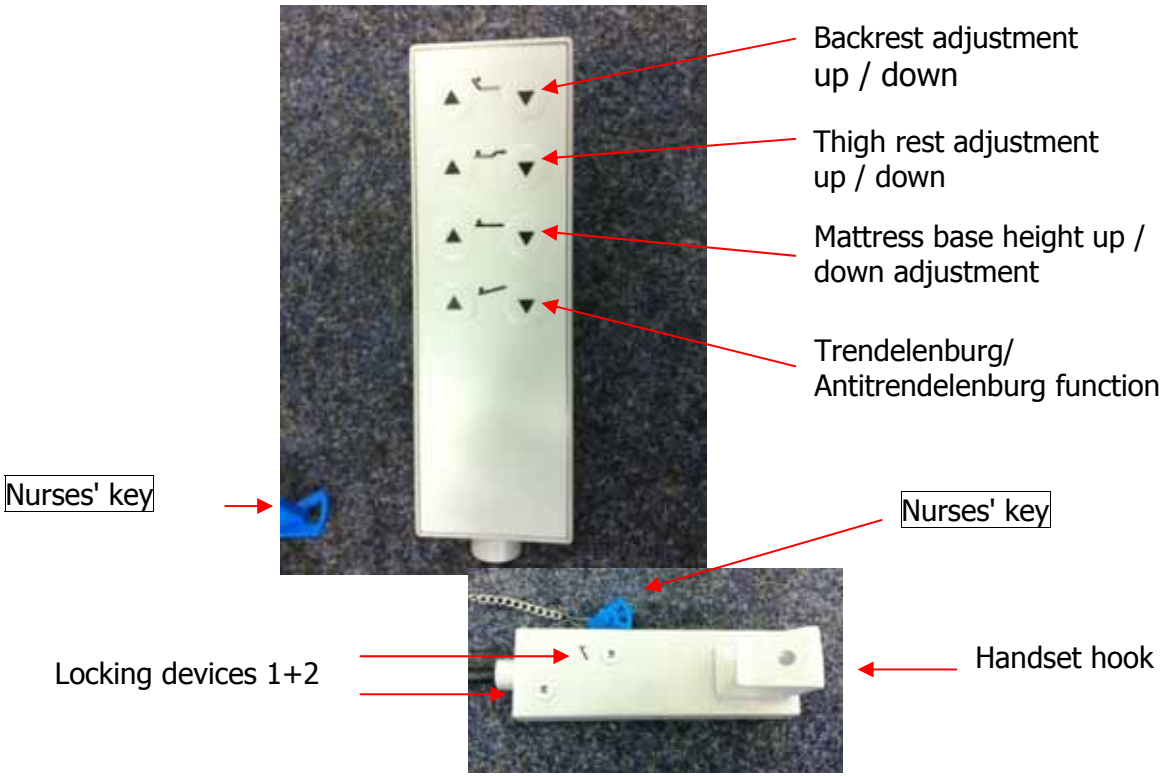
7.1 Overview



1	Head end with integrated height adjustment
2	Foot end with integrated height adjustment
3	Electrically adjustable backrest
4	Electrically adjustable thigh rest
5	Mechanically adjustable thigh rest
6	Handset
7	Nurses' locking key
8	Electric motor unit for backrest with plug-on control unit fitted (safe low voltage)
9	Electric motor unit for thigh rest
10	Mechanical catch fitting for adjusting thigh rest
11	Electric height adjustment motor at head end
12	Electric height adjustment motor at foot end
13	Coiled cable with SMPS power supply transformer box and main cable with power plug
14	Mattress guide
15	Locating sleeve for patient’s lifting pole (as an option)
16	Aluminium side guard (with end caps)
17	Release button for side guard lock
18	Side guard channel
19	Castor with mechanical brake

7.2 Handset with Locking Function

The motorised bed functions can be operated via the handset.
All functions can be locked with the nurses' key.



To avoid damage, the handset should always be hung up on the handset hook (e.g. mattress base or side guard) when not in use.

ATTENTION: Press only one button at a time, as the system could overload and become damaged.

7.3 Locking Function for Handset

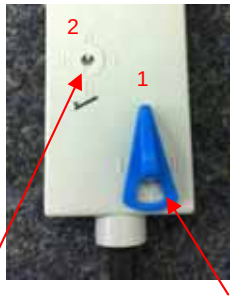
On the back of the handset there are 2 locking devices (1 + 2 see pictures on next page).

All electric adjustment functions can be locked at the same time using the nurses' key supplied with locking device 1.

When locking device 1 and locking device 2 are both released at the same time, the trendelenburg adjustment function of the bed platform is operational and the platform height adjustment function is locked.

ATTENTION: Trendelenburg function and mattress base height adjustment cannot be operated at the same time!

The switching positions I and II are testing settings, used to check the safety during the annual inspection or after repair work, or each time the bed is put into service again.



2: Trendelenburg adjustment function locked

1: Electric adjustment functions released => back-/thigh rest + mattress base height adjustment functions operational

1: All electric adjustment functions locked

2: Trendelenburg adjustment function released

1: All electric adjustment functions released: Back-/thigh rest operational
NOTE: mattress base height adjustment not operational

7.4 Operation of the Side Guards

To use the side guards, lift the upper side guard until it locks into place in the highest position.
To lower the side guard, lift the upper side guard and at the same time push the release button for the side guard lock and lower the side guard.

2. Pull release button and lower side guard!

1. Lift the upper side guard!

The side rail guards are designed only to prevent a person falling out of the bed, under no circumstances should they be climbed or leaned on! When lowering the rails take care not to drop them, they should be lowered carefully.

ATTENTION: If the side guard is in its high position,ensure that it is always safely locked into place!

7.5 Operation of the Castors

All castors on the bed can be braked and must always be in the braked position during normal operation.

Foot pedal to release the brake

Foot pedal to apply the brake

Brake released

Brake applied using foot pedal

ATTENTION: The brakes must only be released to move the bed! Please also refer to the Safety Information!

7.6 Electric Emergency Lowering via the Integrated 9V Battery

7.6.1 Position and Principle of Operation

The power supply unit fitted (item 8, Overview) on the backrest motor is equipped with a 9V block battery, which makes it possible to lower the various electric adjustment functions in the event of a power failure. Please note, however, that this is only possible once per 9V battery, as the capacity of the 9V battery is limited.

After the emergency lowering has been used once, the 9V battery must be replaced with a new one. (Type 6LR61 alkaline manganese battery)
The 9V battery should however be replaced every 2 years even if it has not been used.

7.6.2 Battery Change

To replace, check or remove before lengthy storage of the 9V battery, open the battery compartment on the power supply unit attached to the backrest motor.

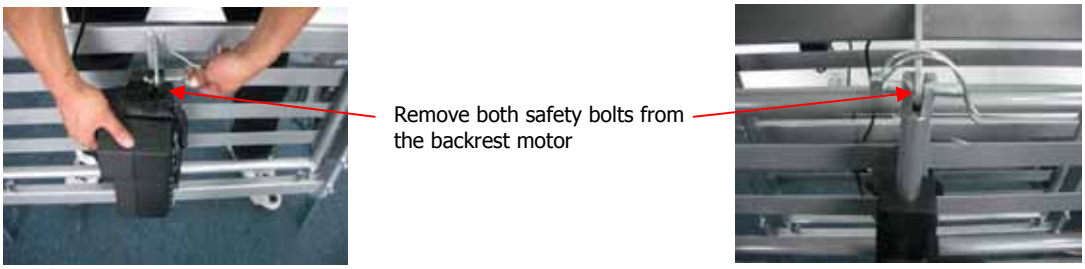
Carry out the battery change as follows:

ATTENTION: Unplug the mains plug!

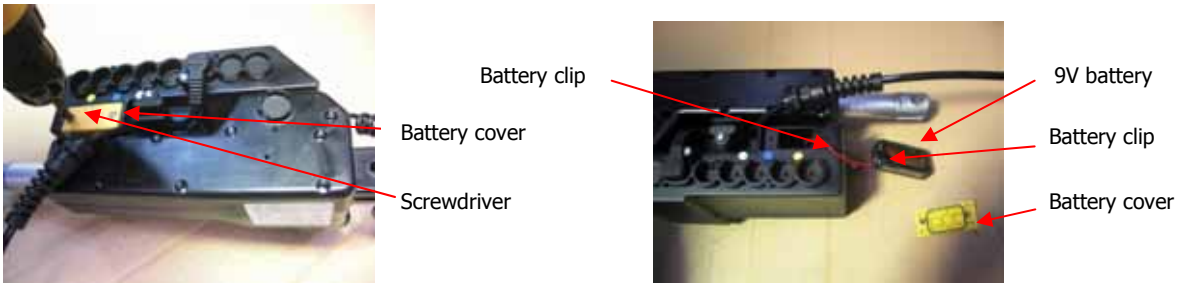
-

Unplug from the low voltage control unit the plug of the connection cable to the SMPS transformer box, the two plugs for the electric motors and the plug for the thigh rest adjustment.
Now remove the motor with the control unit from the mattress base, by removing the two supporting safety bolts from the motor.

ATTENTION: Hold on to the backrest motor when loosening the safety bolts, to prevent it from falling onto the floor.



You can now open the cover (yellow with battery symbol) on the control unit housing with a Philips screwdriver and remove the 9V battery and replace it with a new type 6LR61 alkaline manganese battery.



Close the battery cover again. Be careful not to damage the washer, and avoid over tightening the fastening screws when replacing them.

8 Care, Cleaning and Disinfection

To clean the care bed, wipe the bed by hand with a damp cloth. Use suitable cleaning and conditioning agents for synthetic furniture.
Household cleaners without ammonium or scouring agents are also allowed, but these should have been dermatologically tested.

The bed including electrical components is suitable for automated washing systems.

Solvents and scouring agents are not allowed as these attack and damage the various surfaces of the care bed.

To disinfect: In the homepage of the Robert Koch Institute < http://www.rki.de > you will find a list dated of 31.05.2007of approved and generally accepted disinfection agents and treatments and how they are to be correctly used.

IMPORTANT

Before cleaning and disinfection the mains plug must be unplugged and hung up safely. Plugs for the handset and the motors which are inserted in the control unit MUST remain plugged in. This is necessary to ensure that water does not get into the control system.

9 Trouble Shooting

Before you contact your authorised distributor please use the following table to check:

Fault	Possible cause	Remedy
No response	Mains plug not plugged in	Insert mains plug into mains socket.
	Locking function on handset activated	Unlock handset.
	Handset not plugged in	Insert handset into mattress base motor.
	Motor unit not plugged in	Plug motor unit into mattress base motor.
Adjustment functions transposed	Connecting cables on the connectors transposed.	Check plugs and connectors and change over plugging in locations.
No function after power failure	9V block battery is discharged	Replace 9V block battery.
Bed only moves very slowly	Bed only adjusted via the battery. Mains plug not plugged in	Plug in mains plug and replace the 9V block battery as a precaution.

10 Servicing

10.1 Principles

Operators of care beds are obliged according to MPBetreibV (Operators of Medical Products Ordinance) §4 to guarantee the safe condition of the medical product over their entire service life.

The test according to the regulation EN 62353 contains the following minimum requirements:

- Visual check
- Measurement of leakage resistance
- Measurement of leakage current
- Functional test
- Overall evaluation

The service life of the care bed depends essentially upon the handling and servicing. To guarantee safe operation, a visual and functional test including an electrical test must be carried out at least once a year. For this purpose, proceed according to the technical safety checklist as per regulation EN 62353

IMPORTANT

If you have any doubts about the safety or functioning of the bed or even a part of the bed as a result of the work performed below, the bed should under no circumstances be put into service again.

Contact the supplier or manufacturer in this case.

10.2 List of Technical Safety Checks according to EN 62353

Care bed: Model ECOFIT ULTRA
Serial no.: .....
Location: .....
Person in charge: .....
Inspected by: .....

Item	Instruction for testing	Comment	Yes	No
1.	Is the general condition OK?			
2.	Are the type plates for the bed and the motors legible?			
3.	Is the Instruction Manual available to staff?			
4.	Is the use one for which it was intended and is it safe?			
5.	No surface damage or corrosion?			
6.	Mechanical components and welded joints without faults?			
7.	Are all mechanical connecting elements securely fixed?			
8.	Mattress base underside undamaged?			
9.	Can all adjustment options for the bed be operated without hindrance on site?			
10.	Is the mechanism for locking the thigh rest in place in working order?			
11.	Are the side guard beams free of any fractures, cracks or other damage?			
12.	Do the side guard beams sit securely in their anchorage?			
13.	Has the load test been carried out successfully according to the regulations?			
14.	Are the patient's lifting pole with the grab handle and the lifting pole sleeve undamaged and without any signs of wear?			
15.	Functioning of the side guard beams, do they safely lock into place?			
16.	Do the side guard beams run smoothly in their guide rails?			
17.	Max. distance between the side guard beams 12 cm?			
18.	Height of side guards above the mattress at least 22 cm?			
19.	Have castors including locking brake been tested for safe functioning?			
20.	Mains cable, connecting cables and plugs without damage?			
21.	Fixture available for safe transportation of mains plug?			
22.	Strain relief of the mains cable and handset securely attached?			
23.	Are all plug-in connections securely attached? (Washers without damage?)			
24.	Are cables laid correctly and safely? (No damage)			
25.	Motor housing and mains plug housing without damage?			
26.	Are the thrust pipes of the height adjustment motors undamaged?			
27.	Functional test of the handset: can the buttons be operated properly?			
28.	Functional test of handset locking device: On/Off working correctly?			
29.	Testing of initial fault safety by means of integrated blocking box in handset			
30.	9V block battery OK / expiry date sufficient until next test?			
31.	Protective earth conductor resistance does not apply, as there is no earth conductor available (protective class II)			
32.	Isolation resistance > 7MΩ ? Measured value:	OK?		
33.	Alternative leakage current <= 0.2mA? Measured value:	OK?		
34.	Patient's leakage current according to IEC (Special protection against electric shock) 601-1, Measured value:	OK?		
35.	Is the safe working load adhered to?			
	Overall evaluation of the bed: bed OK?			

Comments: .....
.....

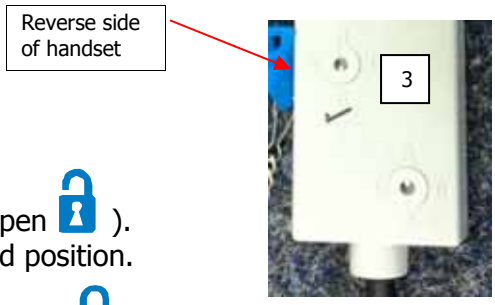
Place / Date : ..... **Inspected by:** .....

Next inspection: ..... **Signature:** .....

10.3 Checking the Initial Fault Safety by means of the Integrated Control Box in the Handset

To check the safety equipment, proceed as follows:

The switching positions I and II are testing settings used only to check the safety during the annual inspection, or after repair work, or each time bed is put into service again.



- Setting switch position 4 (padlock symbol open).
  Move all bed adjustments to a slightly raised position.
- Setting switch position 3 (padlock symbol closed).
  When operating the adjustment buttons, no motorised adjustments should be possible.
- Set switch on the back of the handset to testing position 1 (symbol **I**).)
  When operating the adjustment buttons, no motorised adjustments should be possible.
- Set switch on the back of the handset to testing position 2 (symbol **II**).)
  When operating the adjustment buttons, no motorised adjustments should be possible.

10.4 Measurement of Overall Electrical System

ATTENTION: The measurements described here must only be performed by a qualified electrician or by an electrotechnically trained person, (using suitable measuring and testing devices)

The measurements shall include as a minimum the testing of the housing leakage current and the measurement of the isolation resistance.

The following measured values must be attained:

*Housing leakage current <= 0.2mA
*Isolation resistance <= 7MΩ

During testing the corresponding button on the handset must be kept constantly pressed.

The measurement is to be performed between:

*The control unit and the bed frame
*The control unit and the handset

11 Guarantee

As stated in our Standard Terms and Conditions: We provide a manufacturer's warranty of 24 months from the date of purchase.

12 Service Life and Disposal

The service life of our care beds in domestic use is assumed to be approximately 5 years. This naturally depends upon the manner of use. The carebed is suitable for re-use if all measures of section 6.3 and 10 are taken. Frequent transportation, setting up and adjustment reduce the service life, as do improper treatment, irregular servicing and exceeding the safe working load or the admissible load cycle of the electric motors. The care bed must not be disposed of as normal household waste after the end of its service life. To ensure that it is disposed of in an environmentally compatible way please get in touch with TekVor Care.

13 Technical Specification

13.1 Technical Data (Mechanical)

Safe working load (max. admissible load)	205 kg		
Individual loads of the safe working load	max. weight of patient	170	kg
	Mattress	20	kg
	Accessories	15	kg
	Total	205	kg
Safe load, patient's lifting pole	80 kg		
Max. weight of patient	170 kg		
Max. mattress height:	12 cm		
Length	213,5 cm (in the case of 200 cm long mattress base)		
Width	104 cm (in the case of 90 cm wide mattress base)		
Upper level of head section/foot section	84,5 cm – approx. 127 cm		
Height adjustment of mattress base	continually adjustable electrically from 32,5-75 cm		
Backrest adjustment	continually adjustable electrically up to approx. 70°		
Thigh rest adjustment	continually adjustable electrically up to approx. 30°		
Foot rest in raised position	mechanically, -25°-0° in 4 stages		
Mattress base surface	Steel slatted base		
Aluminium sideguard rails incl. endcaps lowerable on both sides:	197,3x9,5x2,8 cm distance from mattress without load (12 cm) to upper edge of sideguard rail ≥ 22 cm		
Castors	Ø 75mm with individually lockable brake		
Max. castor loading capacity	100 kg (static)		
Unloaden weight	106 kg		
Operating noise:	< 53 db(A) at a distance of 1m		

13.2 Technical Data (Electric)

Power supply unit (LIMOSS)	control unit MC210 + SMPS MC125
Voltage rating	230/240V
Frequency rating	50/60 Hz

Type of current	AC ~
Nominal consumption during operation	250 Watt
Nominal consumption in idle state	0 Watt
Nominal operating time/ Nominal idle time	2 Min. / 18 Min (max. 5 switching cycles/min.)
Primary safety fuse	2.0 A
Battery for emergency lowering	9V block battery (alkaline manganese type 6LR61)
Mattress base motor unit (back/knee)	2x MD120 (Fa. LIMOSS)
Height adjustment motor unit	2x MD120 (Fa. LIMOSS)
Motor unit protection class	IPX6

13.3 Technical Data (Surroundings)

Temperature range during operation	+10°C to + 40°C
Temperature range for storage/transport-	10°C to + 60°C
Humidity of the air	30% to 75% rel.
Air pressure	between 700 and 1060 hPa

13.4 Classification

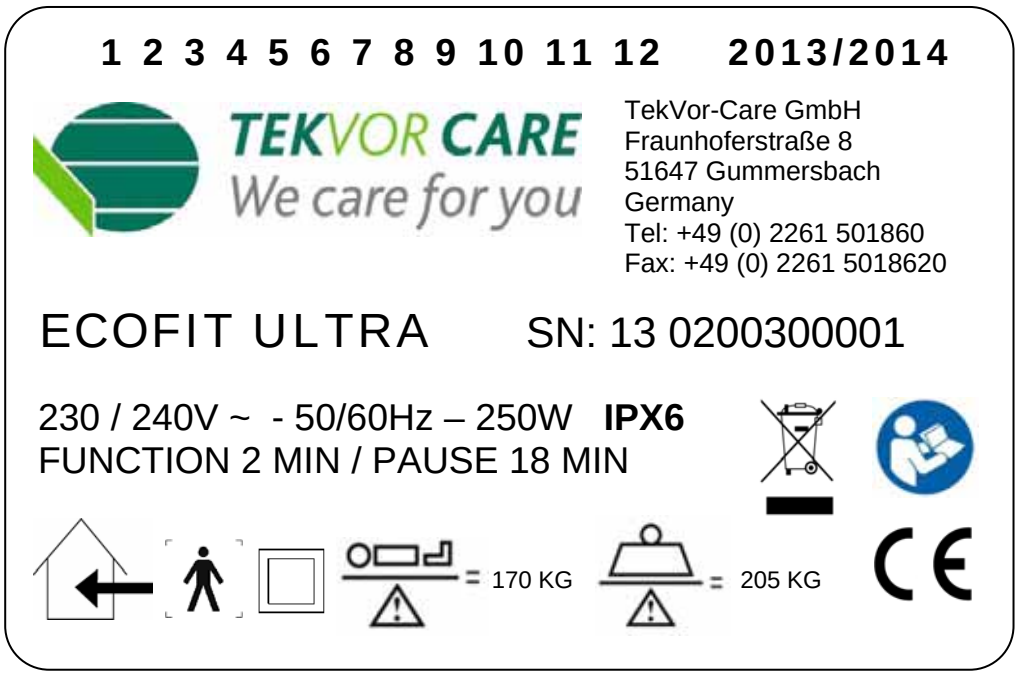
Medical product	Class 1
Degree of protection to DIN EN 60601-1	Type B (protection against electric shock) 
Housing degree of protection to 60259	IPX 6 (suitable for automated washing systems)
Max. duty rating	10%, ON 2 min / OFF 18 min
Max. switching cycles/min	5
Safety inspections	1x per year

13.5 Weights of the Individual Components

Mattress base / Head side (incl. motor)	22.5	kg
Mattress base / Foot side (incl. motor)	21	kg
Head end / Foot end (lifting steel frame incl. motor and white plastic panel or transparent vision board as option)	18.5	kg/each
Aluminium side guards with end caps	16.2	kg/ set of 6pcs.
Patient's lifting pole	4.2	kg (optional accessory)
Grab handles	3,1	kg/pair (optional accessory)
Transporting device	3.4	kg

13.6 Type Plate

Attached to the right inside surface of the mattress base frame. (See Overview)



13.7 Information about electromagnetic emissions

Guidance and manufacturer's declaration - electromagnetic emissions		
The ***care bed*** is intended for use in the electromagnetic environment specified below. The customer or user of the care bed should ensure that it is used in such an environment.		
Emitted interference	**Compliance**	**Electromagnetic Environment - Guidelines**
RF emissions according to CISPR11	Group 1 -	The care bed uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and it is unlikely that nearby electronic devices will be disturbed.
RF emissions according to CISPR11	Class B	The care bed is designed for use in all establishments including domestic establishments and those determined to be directly connected to a public supply network that supplies buildings used for residential purposes
Emissions of harmonics according to IEC61000-3-2	Class A	
Emissions of voltage fluctuations / Flicker according to IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declarations - Electromagnetic Interference Immunity			
The care bed is intended for use in the electromagnetic environment specified below. The customer or user of the *care bed* should ensure that it is used in such an environment.			
Interference Immunity Certification	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic Environment - Guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be wood, concrete or ceramic tile floors. If the floor is covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transients / bursts according to IEC 61000-4-4	± 2 kV for power lines ± 1 kV for input and output lines	± 2 kV for power lines ± 1 kV for input and output lines	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment
Surges according to IEC 61000-4-5	± 1 kV Voltage phase-phase conductor ± 1 kV Voltage phase-ground conductor	± 1 kV Voltage phase-phase conductor ± 1 kV Voltage phase-ground conductor	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment
Voltage dips, short interruptions and supply voltage variations according to IEC 61000-4-11	< 5 % U_T for ½ cycle (> 95% dip) 40 % U_T for 5 cycles (60% dip) 70 % U_T for 25 cycles (30% dip) < 5 % U_T for 5s (> 95% dip)	< 5 % U_T for ½ cycle, 10 ms (> 95% dip) 40 % U_T for 5 cycles, 100 ms (60% dip) 70 % U_T for 25 cycles, 500 ms (30% dip) < 5 % U_T for 5s (> 95% dip)	The quality of the supply voltage should be equivalent to that of a typical business or hospital environment If the user of care bed also requires continued operation during interruptions in energy supply demands, it is recommended to feed the care bed from an uninterruptible power supply or a battery.
Magnetic field of power frequency (50 / 60 Hz) according to IEC 61000-4-8	3 A/m	0.3 A/m	Magnetic fields of power supply frequency should comply with the typical values, as can be found in a business and hospital environment

Guidance and Manufacturer's Declarations – Non-life-support devices
Electromagnetic Interference Immunity

The *care bed* is intended for use in the electromagnetic environment specified below. The customer or user of the *care bed* should ensure that it is used in such an environment.

Interference Immunity Certification	**IEC 60601 Test Level**	**Compliance level**	**Electromagnetic Environment - Guidelines**
Conducted RF interferences according to IEC 61000-4-6 Emitted RF interferences according to IEC 61000-4-3	3 V $_{eff}$ 150 kHz - 80 MHz 3 V/m 80 MHz - 2.5 GHz	3 V $_{eff}$ 3 V/m	Portable and mobile radios, including cables, should not be used closer to the *care bed* than the recommended working clearance that is calculated by the equation for the appropriate frequency. **13.7.1.1 1.1.1.1** **13.7.1.2 1.1.1.2 Recommended working clearance** $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ *for 80 MHz - 800 MHz* $d = [\frac{7}{E_1}]\sqrt{P}$ *for 800 MHz – 2.5 GHz* where P is the power of transmitter in watts (W) according to specifications of the transmitter manufacturer and d is the recommended working clearance in meters (m) Field strengths from fixed RF transmitters should, at all frequencies, according to a site survey [a - Note p. 5] be lower than the level of agreement be [b - Note p. 5] In the vicinity of equipment, bearing the following symbol, interference is possible. 

Note 1: At 80 and 800 MHz, the higher frequency range must be taken.
Note 2: These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from structures, objects and persons.

[a] Field strengths from fixed transmitters, such as base stations of mobile telephones and land mobile radios, amateur radio, AM and FM radio and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength at the location of the care bed exceeds the specified compliance level above, then the care bed should be monitored with respect to its normal operation. If abnormal performance is observed, it may be necessary to take additional measures, such as reorienting or relocating the care bed

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended working clearances between portable and mobile RF communications equipment and the care bed

The care bed is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the *care bed* can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *care bed* as recommended below, according to the maximum output power of the communication device.

Output power of transmitter **W**	**Working clearance according to transmission frequency** **m**		
	150 kHz to 80 MHz at 3 V/m $d = [\frac{3,5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz at 3 V/m** $d = [\frac{3,5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz at 3 V/m** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters not rated in the list above, the working clearance can be determined using the equation, which belongs to the transmitter, where *P* is the nominal output of the transmitter in watts (W) according to specifications of the transmitter manufacturer.

NOTE 1: An additional factor of 10/3 is applied when calculating the recommended working clearance between transmitters in the 80 MHz to 2.5 GHz frequency range in order to reduce the probability that a mobile/portable communication device unintentionally brought into the patient area could lead to interference.

NOTE 2: These guidelines may not apply in all situations. Propagation of electromagnetic waves is affected by absorption and reflection from structures, objects and persons.

All parts and data are continually subject to further development and may therefore deviate from the details given.

14 Declaration of Conformity

DECLARATION OF CONFORMITY
APPENDIX VII
EU DIRECTIVE 93/42/EEC

We, as company **TekVor Care GmbH**
Fraunhoferstraße 8
D-51647 Gummersbach

confirm on our own behalf that

the medical product Handicaped accessible bed / homecare bed models:

ECOFIT ULTRA

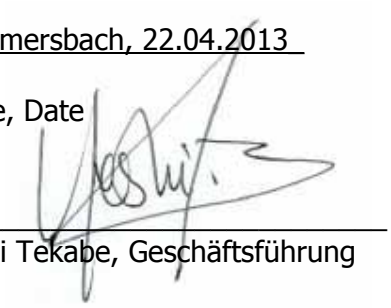
complies with all applicable requirements in Appendix I of the EC directive 93/42/EEC.

Following compliance evaluation process was applied: Appendix VII

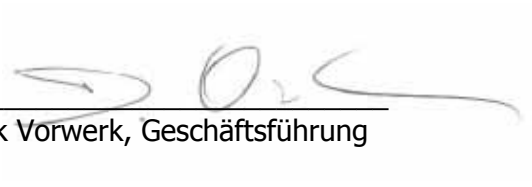
In the event of modification of this product without consultation with the manufacturer, this declaration of conformity will lose its validity.

Gummersbach, 22.04.2013

Place, Date



Yeshi Tekabe, Geschäftsführung



Dirk Vorwerk, Geschäftsführung

23.04.2013

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